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10/553,760	08/21/2006	Anniina Honkanen	019075-00072	5960
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ARENT FOX LLP 1050 CONNECTICUT AVENUE, N.W. SUITE 400 WASHINGTON, DC 20036			WILLIAMS, LELA	
			ART UNIT	PAPER NUMBER
			1787	
			NOTIFICATION DATE	DELIVERY MODE
			07/09/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DCIPDocket@arentfox.com
IPMatters@arentfox.com
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Office Action Summary

Application No.

10/553,760

Applicant(s)

HONKANEN ET AL.

Examiner

LELA S. WILLIAMS

Art Unit

1787

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 April 2010.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1,3-33 and 35 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1,3-33 and 35 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/GS/US)
Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

1. Applicant's amendment filed on March 19, 2010 has been fully considered. The amendment necessitated the new ground of rejection set forth below and therefore, the following action is made final.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1, 3-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claim 1 states "in comparison to a comparable edible product which does not comprise plant sterol" (line 6). The meaning is unclear given that if two products are not similar, how are they comparable?

Claim Rejections - 35 USC § 102

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

5. **Claims 1-4, 7, 8, and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Sarama et al. WO 01/54686.**

Regarding claims 1, 3, 7, 8, and 35; Sarama teaches an edible product comprising a sweetening agent (page 27, third paragraph), and a plant sterol/stanol ester (page 7, third paragraph). The sweetening agent inherently has characteristic properties to mask a bitter, sour and/or astringent taste. The plant sterol/stanol esters component of the reference is present in an amount of 0.0001% to 25% (page 8, third paragraph). Sarama states that a combination of

sterols/stanols is able to disguise adverse flavors (page 8, first paragraph) but does not disclose the ester “to reduce the amount of sweetening agent...in comparison to a comparable edible product which does not comprise the plant sterol”. However, given that the reference discloses the presence of plant sterol/stanol esters in an amount as presently claimed, the plant sterol/stanol esters will inherently “reduce the amount of sweetening agent...in comparison to a comparable edible product which does not comprise the plant sterol”.

Regarding claims 4, Sarama discloses a product as applied to claim 1 wherein the sweetening agent comprises carbohydrates and non-carbohydrates (page 28).

Regarding claim 32, Sarama discloses adding plant sterol ester in an amount of 0.0001% to 25% into an edible product, which will inherently mask a bitter, sour and/or astringent taste of a product which comprises a sweetening agent. The sweetening agent inherently has characteristic properties to mask a bitter, sour and/or astringent taste. Sarama states that a combination of sterols/stanols is able to disguise adverse flavors (page 8, first paragraph) but does not disclose the ester “to reduce the amount of sweetening agent...in comparison to a comparable edible product which does not comprise the plant sterol”. However, given that the reference discloses the presence of plant sterol/stanol esters in an amount as presently claimed, the plant sterol/stanol esters will inherently “reduce the amount of sweetening agent...in comparison to a comparable edible product which does not comprise the plant sterol”.

Regarding claim 33, Sarama discloses a method for preparing an edible product in the form of dietary foods to meet the needs of persons who are obese or diabetic (page 36, third paragraph) comprising carbohydrate sweetening agents and 0.0001% to 25% of plant sterol/stanol esters (page 8, third paragraph). The sweetening agent inherently has characteristic

properties to mask a bitter, sour and/or astringent taste. Sarama states that a combination of sterols/stanols is able to disguise adverse flavors (page 8, first paragraph) but does not disclose the ester “to reduce the amount of carbohydrate sweetening agent...in comparison to a comparable edible product which does not comprise the plant sterol”. However, given that the reference discloses the presence of plant sterol/stanol esters in an amount as presently claimed, the plant sterol/stanol esters will inherently “reduce the amount of carbohydrate sweetening agent...in comparison to a comparable edible product which does not comprise the plant sterol”.

Claim Rejections - 35 USC § 103

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
7. **Claims 5, 6, 9, 11-12, 20-23, and 29-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sarama et al. WO 01/54686.**

Regarding claim 5, Sarama discloses a product as applied to claim 4 above, wherein carbohydrate or non-carbohydrate sweetener agents are added to the product in the amount of 0.1% to 20% (page 28, line 1). The reference does not give the specific amount of each agent used, but does state the amount of sweetener will depend on the particular sweetener used and the sweetness intensity desired (page 27, third paragraph). Given this information, the determination of the amount of sweetener would be considered a result effective variable by one having ordinary skill in the art at the time the invention was made. As such, without showing unexpected results, the claimed amount cannot be considered critical. Accordingly, one of ordinary skill in the art at the time the invention was made would have optimized, by

routine experimentation, the amount of each sweetener needed to obtain the desired product (In re Boesch, 617 F.2d. 272, 205 USPQ 215 (CCPA 1980)), since it has been held that where the general conditions of the claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. (In re Aller, 105 USPQ 223).

Regarding claim 6, Sarama discloses a product as applied to claim 1, but the reference does not disclose the reduced range amount. However, regardless of how the reference achieved the amount, it is significant to note the reference discloses the amount of sweetening agent in the composition is from 0.1% to 20%, which would encompass that of the present invention, thereby achieving a reduced range amount, including that presently claimed.

Regarding claim 9, Sarama discloses a product as applied to claim 1, to be a beverage, such as teas, colas, fruit juice, or near-water (page 21, fourth paragraph). The reference does not teach the viscosity of said beverages; however they are drinks known to be of low viscosity. Knowing that these drinks are usually “thin” and greatly accepted by the consumer as being so, it would have been obvious to one of ordinary skill in the art at the time of the invention to prepare the beverages to have a low viscosity in the Pascal range including as presently claimed, in order to produce a beverage with the known desired thinness/thickness of the final beverage.

Regarding claims 11, 12, 20-23, 29, 30, and 31, Sarama discloses beverage and food products, i.e. milk and juice drinks, ice cream (page 21, third paragraph), which comprises plant sterol ester and a carbohydrate or non-carbohydrate sweetening agent. Sarama discloses that the plant sterol ester compound is particularly useful in such beverages as those containing 0.1% to 40% fruit juices or fruit flavors (berries and citrus are explicitly listed in paragraph 2, page 25)

milks, coffees, teas, and fortified drinks e.g. a liquid meal replacement (page 21, 3rd para.-page 22, 1st para.). The reference also teaches adding flavors such as chocolate (page 26, second paragraph). The disclosure of a “milk based [flavor] drink” is not explicitly stated, however given the disclosure of the drinks/flavors, it would have been obvious to one of ordinary skill to combine milk with chocolate to yield a milk based cocoa drink or milk with coffee thus yielding a milk based coffee drink. The mixtures of milk/cocoa and milk/coffee are beverages that have long been established and accepted. The specific amounts of plant sterol and carbohydrate or no-carbohydrate sweetening agents used in the individual drinks/food products are not disclosed and the amount of citrus fruit juice falls slightly outside of the claimed range of at least 50%, however the general ranges of 0.0001% to 25% of plant sterol/stanol esters and 0.1% to 20% of carbohydrate or no-carbohydrate sweetening, which include sucrose (page 28) are given, it would have been within the skill level of one of ordinary skill in the art to develop a beverage, including the presently claimed beverage, with a suitable amount of additives, including citrus fruit juice, to achieve the desired taste of the final product.

One of ordinary skill would have optimized, by routine experimentation, a desired amount of plant sterol, sweetener, either carbohydrate or non-carbohydrate, and fruit juice (In re Boesch, 617 F.2d. 272, 205 USPQ 215 (CCPA 1980)). Since it has been held that where the general conditions of the claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. (In re Aller, 105 USPQ 223). As such, without showing unexpected results, the claimed amount cannot be considered critical.

The sweetening agent, including sucrose, inherently has characteristic properties to mask a bitter, sour and/or astringent taste. Although Samara does not disclose the ester “to reduce the

amount of carbohydrate sweetening [sucrose] agent...in comparison to a comparable edible product which does not comprise the plant sterol”, given that the reference discloses the presence of plant sterol/stanol esters in an amount as presently claimed, the plant sterol/stanol esters will inherently “reduce the amount of carbohydrate sweetening agent [sucrose]...in comparison to a comparable edible product which does not comprise the plant sterol”.

It is noted that the presently claimed amount of non-carbohydrate in claim 23 is less than that disclosed by Sarama, however, as the flavor is a variable that can be modified, among others, by adjusting the amount of the additives or the type of sweetener, the precise amount would have been considered a result effective variable by one having ordinary skill in the art at the time the invention was made. As such, without showing unexpected results, the claimed amount cannot be considered critical. Accordingly, one of ordinary skill in the art at the time the invention was made would have optimized, by routine experimentation, the amount of plant sterol ester and sweetener agent in Sarama to obtain the desired flavor (In re Boesch, 617 F.2d. 272, 205 USPQ 215 (CCPA 1980)). Since it has been held that where the general conditions of the claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. (In re Aller, 105 USPQ 223). Therefore, given the presently claimed amount could have been determined by one of ordinary skill in the art without undue experimentation, the presently claimed amount is not considered to confer patentability to the claims.

8. Claims 10 and 13-18 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Sarama et al. WO 01/54686 in view of Yoon et al. WO 02/28204.

Regarding claims 10, 13-18; Sarama discloses adding plant sterol ester in an amount of 0.0001% to 25% and a carbohydrate or non-carbohydrate sweetening agent in an amount of 0.1% to 20% to a milk beverage (page 21, 3rd para.-page 22, 1st para.) and other dairy products such as ice cream, milkshakes, and milk products (page 21, 3rd para.). The sweetening agent inherently has characteristic properties to mask a bitter, sour and/or astringent taste and although Samara does not disclose the ester “to reduce the amount of carbohydrate sweetening agent...in comparison to a comparable edible product which does not comprise the plant sterol”, given that the reference discloses the presence of plant sterol/stanol esters in an amount as presently claimed, the plant sterol/stanol esters will inherently “reduce the amount of carbohydrate sweetening agent...in comparison to a comparable edible product which does not comprise the plant sterol”.

Sarama disclosure of a milk beverage/products and additive amounts are general and it does not specifically list a cereal milk based drink/product, soy products, or the specific amounts of sweetener agent.

Yoon teaches adding plant sterol to various beverages (page 1, line 5) including water, juices, coffee, tea, milk, and soy milk (page 9, line 30).

Given that the reference teaches the use of soy milk, as well as juices and coffee, it would have been obvious to one of ordinary skill in the art to combine soy with the other milk beverages/ products to enhance the nutritional value of fruit juice and coffee drinks.

It is noted that the presently claimed amount of non-carbohydrate in claims 14, 16, and 18 is less than that disclosed by Sarama, however, as the flavor is a variable that can be modified, among others, by adjusting the amount of the additives or the type of sweetener, the

precise amount would have been considered a result effective variable by one having ordinary skill in the art at the time the invention was made. As such, without showing unexpected results, the claimed amount cannot be considered critical. Accordingly, one of ordinary skill in the art at the time the invention was made would have optimized, by routine experimentation, the amount of plant sterol ester and sweetener agent in Sarama to obtain the desired flavor (In re Boesch, 617 F.2d. 272, 205 USPQ 215 (CCPA 1980)). Since it has been held that where the general conditions of the claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. (In re Aller, 105 USPQ 223). Therefore, given the presently claimed amount could have been determined by one of ordinary skill in the art without undue experimentation, the presently claimed amount is not considered to confer patentability to the claims.

9. Claims 19, 24-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sarama et al. WO 01/54686 in view of Vulpson et al. WO 00/41491.

Sarama discloses adding plant sterol ester in an amount of 0.0001% to 25% and a sweetener agent in an amount of 0.1% to 20% to a milk beverage. The sweetening agent inherently has characteristic properties to mask a bitter, sour and/or astringent taste and although Samara does not disclose the ester “to reduce the amount of carbohydrate sweetening agent...in comparison to a comparable edible product which does not comprise the plant sterol”, given that the reference discloses the presence of plant sterol/stanol esters in an amount as presently claimed, the plant sterol/stanol esters will inherently “reduce the amount of carbohydrate

sweetening agent...in comparison to a comparable edible product which does not comprise the plant sterol”.

Sarama's disclosure of a milk beverage and additive amounts are general and it does not specifically list a fermented milk based drink or the type of sweetener agent.

Vulpson teaches adding plant sterols to fermented milk products such as yoghurt (page 1, line 12). The reference discloses a yoghurt product based on whey protein and plant sterols (page 23, lines 21-23) and also discloses the use of soymilk in the yoghurt process (page 35, line 2). The reference does not expressly disclose a cereal-based yoghurt product, however it does teach that “rice and soybeans are the most common raw materials for the production of fermented foods in many Eastern countries” (page 7, line 17-20). Therefore, given it is disclosed as common knowledge in the art to have rice (which is a cereal) based yoghurt products, one of ordinary skill in the art would have found it obvious to produce cereal-based yoghurt.

One of ordinary skill in the art would have been motivated to combine the teaching of Sarama with those of Vulpson in order to produce a food/drink product which has not only good taste but also added health benefits.

It is noted that the presently claimed amount of non-carbohydrate in claims 25 and 28 is less than that disclosed by Sarama, however, as the flavor is a variable that can be modified, among others, by adjusting the amount of the additives or the type of sweetener, the precise amount would have been considered a result effective variable by one having ordinary skill in the art at the time the invention was made. As such, without showing unexpected results, the claimed amount cannot be considered critical. Accordingly, one of ordinary skill in the art at the time the invention was made would have optimized, by routine experimentation, the amount

of plant sterol ester and sweetener agent in Samara to obtain the desired flavor (In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980)). Since it has been held that where the general conditions of the claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. (In re Aller, 105 USPQ 223). Therefore, given the presently claimed amount could have been determined by one of ordinary skill in the art without undue experimentation, the presently claimed amount is not considered to confer patentability to the claims.

Response to Amendment

10. Claims 1, 3-33, and 35 are currently pending. Claims 2 and 34 are cancelled.
11. Applicant's amendment is sufficient to overcome the objections set forth in the previous office action; therefore the objections have been withdrawn.
12. Applicant's amendment is sufficient to overcome the 35 U.S.C. §112, second paragraph and 35 U.S.C §101 rejections set forth in the previous office action, therefore the rejections have been withdrawn.

Response to Arguments

Applicant's arguments filed March 19, 2010 have been fully considered but they are not persuasive. Applicant states that Samara discloses removing the unacceptable flavor associated with L-arginine and does not disclose "the aspect of reducing the amount of sweetener" (page 17-18) is noted. The reference does teach removing the unacceptable flavor associated with L-arginine, however, given that the reference discloses the presence of plant sterol/stanol esters in an amount as presently claimed, the plant sterol/stanol esters will inherently reduce the amount

of sweetening agent in the edible product in comparison to a comparable edible product which does not comprise the plant sterol.

Further, Applicant has described the product with parameters i.e., “in comparison to a comparable edible product which does not comprise the plant sterol”, which cannot be measured by the office for prior art comparison, because the office is not equipped to manufacture prior art products and compare them for patentability purposes. Therefore, the burden is shifted to the applicant to show that the prior art product is different.

Regarding applicant's argument of Yoon (WO 02/28204), note that while Yoon does not disclose all the features of the present claimed invention, the reference is used as a teaching reference, and therefore, it is not necessary for the secondary references to contain all the features of the presently claimed invention, *In re Nievelt*, 482 F.2d 965, 179 USPQ 224, 226 (CCPA 1973), *In re Keller* 624 F.2d 413, 208 USPQ 871, 881 (CCPA 1981). Rather Yoon is used teach a certain concept, namely that plant sterols are known to be added to various edible products, and in combination with the primary reference, discloses the presently claimed invention.

Regarding applicant's argument of Vulpson (WO 00/41491) note that while Vulpson does not disclose all the features of the present claimed invention, the reference is used as a teaching reference, and therefore, it is not necessary for the secondary references to contain all the features of the presently claimed invention, *In re Nievelt*, 482 F.2d 965, 179 USPQ 224, 226 (CCPA 1973), *In re Keller* 624 F.2d 413, 208 USPQ 871, 881 (CCPA 1981). Rather Vulpson is

used teach a certain concept, namely that plant sterols are known to be added to fermented milk, rice, and soya yoghurt products, and in combination with the primary reference, discloses the presently claimed invention.

Conclusion

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LELA S. WILLIAMS whose telephone number is (571)270-1126. The examiner can normally be reached on Monday to Thursday from 7:30am-5pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Callie Shosho can be reached on 571-272-1123. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LELA S. WILLIAMS
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